**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| JOHNSON & JOHNSON *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>SAMSUNG BIOEPIS CO. LTD.,<br><br>Defendant. | Civil Action No. 25-01439 (GC) (JTQ)<br><br>**OPINION**<br><br>**FILED UNDER TEMPORARY SEAL**[1] |

**CASTNER, District Judge**

**THIS MATTER** comes before the Court upon Plaintiffs Johnson & Johnson and Janssen Biotech, Inc.'s Motion for a Preliminary Injunction. (ECF No. 7.) Defendant Samsung Bioepis Co. Ltd. opposed, and Plaintiffs replied. (ECF Nos. 19, 23.) The Court held oral argument on Plaintiffs' Motion on April 1, 2025. The Court has carefully considered the parties' submissions and arguments. For the reasons set forth below, and other good cause shown, Plaintiffs' Motion for a Preliminary Injunction is **DENIED**. While Plaintiffs have shown a likelihood of success on the merits, Plaintiffs have not shown that they will be irreparably harmed by the Court denying their request for such extraordinary relief.

[1] This Opinion is filed under temporary seal because the parties have filed their submissions in connection with Plaintiffs' Motion for a Preliminary Injunction under seal. (See ECF Nos. 8, 19, 23.) Consistent with the Magistrate Judge's February 7, 2025 Order, the parties shall file any motions to seal within fourteen (14) days of the entry of this Opinion and its accompanying Order.

## I. BACKGROUND

### A. Factual Background[2]

Plaintiffs developed ustekinumab, a monoclonal antibody used to treat plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.[3] (ECF No. 2 ¶¶ 1, 16.) Ustekinumab is a biologic; biologics are a "class of medications that derive from natural sources, such as living cells and entities." (ECF No. 19 at 11.[4]) Biologics are "far more costly to manufacture" than traditional "small molecule" pharmaceuticals. (*Id.* at 11.)

Plaintiffs sell ustekinumab under the brand name Stelara. (ECF No. 2 ¶ 16.) Over the course of two decades, Plaintiffs invested hundreds of millions of dollars in the research and development of Stelara. (*Id.*) Stelara was initially approved by the United States Food and Drug Administration (FDA) for treatment of plaque psoriasis in 2009 and was later approved for treatment of additional conditions, including psoriatic arthritis, Crohn's disease, and ulcerative colitis. (*Id.*) Stelara has been used by hundreds of thousands of patients, (*id.* ¶ 16), and global sales of Stelara have exceeded $70 billion (ECF No. 19-4 ¶ 66). Annual U.S. sales of Stelara peaked at $7 billion before declining to $6.7 billion in 2024. (ECF No. 19-4 ¶ 30.) Globally, "sales of Stelara reached $10.9 billion in 2023 and declined to $10.4 billion in 2024." (*Id.*)

Defendant Samsung develops and manufactures biologics. (ECF No. 19 at 11.) Plaintiffs allege that Samsung "sought to piggyback off [Plaintiffs'] extraordinary investment by creating a

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[2] The relevant factual background is drawn from Plaintiffs' Complaint and the parties' submissions related to Plaintiffs' Motion for a Preliminary Injunction. (ECF Nos. 1, 2, 8, 19, and 23.)

[3] For ease of reference only, the Court refers to Johnson & Johnson and Janssen collectively as "Plaintiffs."

[4] Page numbers for record cites (*i.e.*, "ECF Nos.") refer to the page numbers stamped by the Court's e-filing system and not the internal pagination of the parties.

copy of" Stelara. (ECF No. 2 ¶ 17.) Samsung did so, Plaintiffs contend, by seeking regulatory approval of a biosimilar of Stelara through an abbreviated Biologics License Application (BLA). (*Id.*) Biosimilars "serve a similar purpose to generic versions of small molecule drugs, in that they are highly similar to a biologic medication already approved by the FDA." (ECF No. 19-3 ¶ 10 (internal quotation marks omitted).) Proceeding via an abbreviated BLA allowed Samsung to use data from Plaintiffs' clinical trials for Stelara, which already established the safety and efficacy of ustekinumab. (ECF No. 2 ¶ 17.) On March 23, 2023, Samsung sought FDA approval of its ustekinumab biosimilar (now called Pyzchiva). (*Id.*)

Samsung sought approval of its ustekinumab biosimilar even though Plaintiffs hold "numerous patents" related to ustekinumab. (*Id.* ¶ 2.) Plaintiffs maintain that Samsung's Pyzchiva is covered by "one or more" of Plaintiffs' patents.[5] (*Id.* ¶ 17.) As a result, the parties became involved in separate litigation—Samsung challenged one of Plaintiffs' patents before the Patent Trial and Appeal Board[6] and Plaintiffs sued Samsung in The Hague, Netherlands.[7] (*Id.* ¶ 18.)

### 1. *The Settlement Agreement*

On July 25, 2023, the parties entered into an agreement (the Settlement Agreement[8]) to resolve their ustekinumab-related disputes. (*Id.* ¶ 19.) The Settlement Agreement "provid[es]

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[5] Samsung submits that "[Plaintiffs'] patent on ustekinumab's composition– U.S. Patent No. 6,902,734 – expired on September 25, 2023," and further notes that "[w]hile [Plaintiffs] hold[] other patents related to Stelara, some expiring as late as 2039, the September 2023 expiration was the practical end of their exclusivity period." (ECF No. 19 at 11.)

[6] *See Samsung Bioepis Co., Ltd. v. Janssen Biotech, Inc.*, IPR No. 2023-01103.

[7] *See Janssen Biotech, Inc. v. Samsung Bioepis NL B. V*, No. C/09/648912 KG ZA 23-477.

[8] The Settlement Agreement with Samsung was one of several agreements in which Plaintiffs authorized different biosimilar manufacturers to enter the market with Stelara biosimilars at specific dates and under specific conditions. (ECF No. 2 ¶ 22.)

Samsung a limited patent license . . . and specif[ies] the date and other conditions for Samsung to enter the market in the United States." (*Id.*) Thus, Samsung was granted the right to sell its ustekinumab biosimilar, Pyzchiva (referred to in the Settlement Agreement as the SB17 Product), in the United States beginning on February 22, 2025. (*Id.* ¶¶ 20-21.) The Settlement Agreement also provides that "[f]or the purpose of this Agreement only, Samsung agrees that absent the Patent License, the SB17 Product would infringe on one or more valid and enforceable claims of the asserted Licensed Patents." (ECF No. 8 at 11.)

Section 3.1 of the Settlement Agreement generally prohibits Samsung from sublicensing its rights,[9] subject to the following three exceptions set forth in Section 3.2: "(a) contract manufacturers to manufacture SB17 Product solely on behalf of [Samsung], (b) commercialization partners to import, sell and offer to sell SB17 Product on behalf of [Samsung], and (c) co-manufacture and commercialization partners to co-manufacture SB17 in coordination with Samsung and commercialize SB17 in the [United States] in the account of Samsung or the co-manufacture and commercialization party[.]" (ECF No. 8-3 at 6, § 3.2.) The Settlement Agreement "requires Samsung to provide [Plaintiffs] with a 'true and complete copy' of each sublicense within 30 days of execution with only narrow rights of redaction for 'confidential and proprietary' information 'not necessary to determine the scope . . . or compliance with the terms of this Agreement.'" (ECF No. 2 ¶ 24 (quoting ECF No. 8-3 at 6, § 3.2).) The Settlement Agreement also contains an anti-assignment clause, which prohibits either party from assigning any interest without the prior written consent of the other party. (ECF No. 8-3 at 14-15, § 10.12.)

[9] Specifically, Section 3.1 provides that Plaintiffs grant to Samsung "a royalty-free, non-transferrable . . . non-exclusive, revocable [] license [] without the right to sublicense[.]" (ECF No. 8-3 at 5, § 3.1.)

The parties dispute the scope of the term "SB17 Product" as used in the Settlement Agreement. Plaintiffs argue that "SB17 Product" is limited to "two subcutaneous presentations" of Samsung's branded product Pyzchiva, which were submitted to the FDA under BLA No. 761373. (ECF No. 8 at 11.)[10] Samsung, however, explains that at the time the Settlement Agreement was executed, the referenced BLA No. 761373 covered three presentations of ustekinumab—two pre-filled syringes for subcutaneous use and one single-dose vial for intravenous use. (ECF No. 19 at 13-14; ECF No. 19-3 ¶ 15.) However, Samsung asserts that it "subsequently split one presentation from the original BLA No. 761363 into a separate BLA No. 761425, and both BLAs were approved and assigned the nonproprietary name ustekinumab-ttwe."[11] (ECF No. 19 at 14.) Samsung's decision to split its ustekinumab-ttwe application into two separate BLAs is consistent with how Stelara was submitted and approved by the FDA under separate BLAs for its subcutaneous and intravenous presentations. (ECF No. 19-3 ¶ 15.) Samsung contends that the FDA-approved "Pyzchiva" encompasses all three presentations of ustekinumab-ttwe developed by Samsung. (ECF No. 19 at 13-15.)

Plaintiffs allege that, in March 2024, "Samsung sought to amend the [Settlement] Agreement to expand the definition of SB17 Product." (ECF No. 2 ¶ 28.) While the Settlement Agreement defines SB17 as "Samsung's ustekinumab biosimilar product," Plaintiffs claim that "Samsung tried to convert the singular 'product' . . . in the definition to the plural 'products,' and to include further biologics license applications for 'ustekinumab biosimilar products.'" (*Id.*)

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[10] The term "presentation" refers to a drug's dosage form and strength. (ECF No. 19 at 14; ECF no. 19-3 ¶ 15.)

[11] The FDA names biosimilars by adding a four-letter suffix to the nonproprietary name of the reference product. (ECF No. 19-3 ¶ 20.) Thus, Samsung's biosimilar is referred to as ustekinumab-***ttwe***.

However, Samsung's proposed amendment to the Settlement Agreement was never executed. (*Id.*) Notwithstanding these issues, Samsung began selling Pyzchiva in the United States on February 22, 2025, and Plaintiffs do not seek to enjoin Samsung from continuing to do so. (*See* ECF No. 7; ECF No. 8 at 43 ("[T]he preliminary injunction would not restrain Samsung's lawful activity of selling its branded product, [Pyzchiva], under BLA No. 761373[.]").)

**2. *The Samsung-Sandoz Agreements***

Having secured a license from Plaintiffs, Samsung moved toward commercializing its SB17 product in the United States. (ECF No. 19 at 15.) In September 2023, Sandoz AG announced that it had entered into a Development and Commercialization Agreement with Samsung (Commercialization Agreement) for the sale of Pyzchiva. (ECF No. 8-3 at 31.) Under the Commercialization Agreement, Sandoz was to "market, promote, distribute, offer for sale, sell, have sold, import, export or otherwise commercialize or exploit for profit" Samsung's ustekinumab biosimilar. (ECF No. 19-5 at 27, § 1.37.) According to Sandoz, it had the "exclusive rights to commercialize the biosimilar SB17 ustekinumab in the US, Canada, EEA, Switzerland, and UK." (ECF No. 8-3 at 31-32.) After announcing that the FDA approved Pyzchiva on July 1, 2024, Samsung and Sandoz also entered into a Sublicense Agreement, dated July 26, 2024 (Sandoz Sublicence Agreement), under which "Samsung granted Sandoz 'an exclusive, non-transferable . . . royalty-free license' to any patent rights owned or controlled by Samsung that, absent a license, would be infringed by the exploitation of SB17." (ECF No. 19 at 15-16; ECF No. 8-3 at 105.) The FDA-approved packaging for Pyzchiva provides that Pyzchiva is *manufactured by* Samsung and *manufactured for* Sandoz. (ECF No. 2 ¶ 26.)

Although Samsung provided Plaintiffs a copy of the Sandoz Sublicense Agreement on August 18, 2024, Samsung did not provide Plaintiffs a copy of the Commercialization Agreement (which was incorporated by reference into the Sublicense Agreement). (*Id.* ¶ 31.) Plaintiffs sought

to obtain the Commercialization Agreement and notified Samsung that at least one provision of the Sandoz Sublicence Agreement was unlawful because it purported to give Sandoz the right to sublicense. (*Id.* ¶ 33.) Plaintiffs made several unsuccessful attempts to obtain the Commercialization Agreement. (*Id.* ¶¶ 33-34.) On February 7, 2025, Samsung produced a copy of the Commercialization Agreement, but Plaintiffs contend that Samsung's production was "heavily redacted," "missing many sections and terms," and "missing attachments and amendments." (ECF No. 8 at 21.)

### 3. *The Samsung-Quallent Agreements*

On November 1, 2024, Samsung and Sandoz entered into a Private Label Distributor Agreement (PLD Agreement) with Quallent Pharmaceuticals Health LLC. (ECF No. 2 ¶ 35; ECF No. 19-5 at 113.) Quallent is a "Cayman Islands-based subsidiary of the Cigna Group, a healthcare conglomerate." (ECF No. 2 ¶ 5.)[12] The PLD Agreement provides that "Samsung 'shall manufacture' SB17, Sandoz 'shall supply' SB17, and Quallent 'shall distribute the products as a commercialization partner of [Samsung] and Sandoz' in the U.S. 'under [Quallent's] label.'" (ECF No. 19 at 16.) That same day, Samsung and Quallent also entered into a sublicense agreement (Quallent Sublicence Agreement), under which Samsung granted "Quallent rights to coordinate the manufacturing and commercialization of Samsung's biosimilar product under Quallent's private label in the U.S."[13] (ECF No. 19-4 ¶ 16.) Samsung also granted Quallent a "non-exclusive,

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[12] Plaintiffs assert that the "Cigna Group, of which Quallent is a member, is a vertically integrated health conglomerate that includes (i) the fourth largest health insurer in the United States, (ii) one of the largest health care providers in the United States, (iii) one of the largest pharmacy chains in the United States, and (iv) a pharmacy benefits manager ('PBM')—a company that decides what prescriptions will be reimbursed—that controls approximately 23% of prescriptions in the United States." (ECF No. 8 at 9.)

[13] "A 'private-label biosimilar' refers to a biosimilar medication produced by one company but marketed under another company's brand name." (ECF No. 8-1 ¶ 12.)

non-transferable sublicense . . . to sell, offer for sale and import the SB17 Product under Quallent's own label" subject to the terms of the Settlement Agreement between Plaintiffs and Samsung. (ECF No. 8-3 at 140.) Samsung's agreements with Quallent followed a September 2024 announcement from the Cigna Group's healthcare provider, Evernorth Health Services, that it would offer a Stelara biosimilar for $0 out-of-pocket for eligible patients beginning in early 2025. (ECF No. 8-3 at 148.)

As with the Commercialization Agreement, Samsung provided Plaintiffs a redacted version of the PLD agreement on February 7, 2025, but Plaintiffs maintain that the production was heavily redacted and inadequate. (ECF No. 2 ¶ 47.) Plaintiffs "repeatedly sought to engage with Samsung, asking Samsung to terminate its unauthorized agreement with Quallent, provide the missing documentation, and otherwise commit to adhering going forward to all obligations under the Agreement." (*Id.* ¶ 53.) Dissatisfied with Samsung's response, Plaintiffs brought this suit.

#### 4. *The Stelara Biosimilar Market*

There are currently seven Stelara biosimilars approved by the FDA. (ECF No. 19-4 ¶ 13.) In January 2025, the first ustekinumab biosimilar, Wezlana, entered the market. (*Id.*) Wezlana is a private label product offered "through a sole-provider distribution arrangement with Optum Health's Nuvaila (both part of the UnitedHealth Group network, one of the largest in the country)." (*Id.* ¶ 45.) Along with Pyzchiva and Wezlana, there are at least two other biosimilars currently on the market, with more expected to launch in 2025. (*Id.* ¶ 13.)

### B. Procedural Background

On February 24, 2025, Plaintiffs filed their two-count Complaint for breach of contract (Count 1) and breach of the implied covenant of good faith and fair dealing (Count Two).[14] (ECF

[14] The Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332.

No. 2 ¶¶ 62-79.) Plaintiffs seek preliminary and permanent injunctive relief, along with compensatory damages, costs, interest, and attorneys' fees. (*Id.* at 29-30.)

Along with their Complaint, Plaintiffs filed a Motion for an Order to Show Cause for Preliminary Injunction and Alternative Service. (ECF Nos. 7-9.) On February 26, 2025, the Magistrate Judge granted Plaintiffs' request to use alternative service to serve Samsung, (ECF No. 11), and Plaintiffs served Samsung that same day. (ECF No. 13.) In terms of preliminary injunctive relief, Plaintiffs seek an order: (1) enjoining Samsung from "purporting to authorize or supply a certain private label distributor for a private label product from that distributor during the pendency of this action"; and (2) requiring Samsung to comply with certain disclosure requirements in the parties' Settlement Agreement. (ECF No. 7.)

On February 2, 2025, Samsung agreed to delay the launch of the Quallent private label product by 60 days, to April 3, 2025, as a "demonstration of Samsung's good faith willingness to resolve this matter." (ECF No. 8-3 at 307.) The Court set an initial hearing date of March 24, 2025, but the parties raised various scheduling conflicts. On March 24, 2025, the parties notified the Court that Samsung had agreed not to launch the Quallent private label product until at least May 1, 2025. (ECF No. 39.) The Court heard oral argument on Plaintiffs' Motion on April 1, 2025.[15]

## II. LEGAL STANDARD

### A. Preliminary Injunction

Preliminary injunctive relief "is an extraordinary remedy and should be granted only in limited circumstances." *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004)

[15] The parties declined to present live witnesses during the hearing, instead opting to rest on their papers and attorney argument.

(internal quotation marks and citation omitted). A primary purpose of a preliminary injunction is "maintenance of the status quo until a decision on the merits of a case is rendered." *Acierno v. New Castle Cnty.*, 40 F.3d 645, 647 (3d Cir. 1994). A plaintiff seeking a preliminary injunction must establish that (1) it is reasonably likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest. *See Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3rd Cir. 2017); *see also HR Staffing Consultants, LLC v. Butts*, Civ. No. 15-3155, 2015 WL 3492609, at *7 (D.N.J. June 2, 2015) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). If a plaintiff meets the first two factors, the court "then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Reilly*, 858 F.3d at 179. "Because a 'preliminary injunction is an extraordinary and drastic remedy,' the movant bears the burden of making '*a clear showing*.'" *Delaware State Sportsmen's Ass'n, Inc. v. Delaware Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 202 (3d Cir. 2024) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)) (emphasis in original).

## III. DISCUSSION[16]

### A. Likelihood of Success on the Merits

"To demonstrate a likelihood of success on the merits, [a p]laintiff must show that [it] 'can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not).'" *Tracey v. Recovco Mortg. Mgmt. LLC*, 451 F. Supp. 3d 337, 342 (D.N.J.

[16] The Court applies the law of the Third Circuit, rather than of the Federal Circuit, because Plaintiffs' claims sound in contract (not patent) law. *See Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 393 (D. Del.), *aff'd sub nom. Cipla Ltd. v. Amgen Inc*, 778 F. App'x 135 (3d Cir. 2019) (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578 (3d Cir. 2002)).

2020) (citing *Reilly*, 858 F.3d at 179). Thus, a moving party must only show a "reasonable probability of eventual success in the litigation." *Reilly*, 858 F.3d at 176. "[W]hether a party has met this threshold will necessarily vary with the circumstances of each case . . . [and] the elements of the movant's claims. . . ." *Fres-co Sys. USA, Inc. v. Hawkins*, 690 F. App'x 72, 77 (3d Cir. 2017). The Court addresses whether Plaintiffs are likely to succeed on the merits of their claims for breach of contract and for breach of the covenant of good faith and fair dealing in turn.

**1. *Breach of Contract***

To sustain a claim for breach of contract under New Jersey law,[17] a plaintiff must allege: "(1) a contract between the parties; (2) a breach of that contract; (3) damages flowing therefrom; and (4) that the party stating the claim performed its own contractual obligations." *Touzot v. ROM Dev. Corp.*, Civ. No. 15-6289, 2016 WL 1688089, at *7 (D.N.J. Apr. 26, 2016) (quoting *Frederico v. Home Depot*, 507 F.3d 188, 203 (3d Cir. 2007)).

Plaintiffs contend that Samsung breached the Settlement Agreement by: (1) authorizing Quallent to sell a private label Stelara biosimilar; and (2) repeatedly failing to comply with its disclosure obligations under the Settlement Agreement. (*See* ECF No. 8 at 23-31.) As to the second point, Samsung argues that Plaintiffs have not shown how the breach of the disclosure obligations has a causal nexus to the irreparable harms articulated by Plaintiffs. The Court agrees, as Plaintiffs have not pointed to any basis on which the Court could conclude that Plaintiffs' potential harm, such as market share loss, is related in any way to Samsung's failure to comply with the disclosure obligations of the Settlement Agreement. *See CommScope, Inc. v. Rosenberger Tech. (Kunshan) Co.*, Civ. No. 2021 WL 1560717, at *4 (D.N.J. Apr. 20, 2021) ("The plaintiff must

[17] The Settlement Agreement contains a New Jersey choice of law provision. (ECF No. 8-3 at 12, § 10.3.)

further demonstrate a causal connection between the harm alleged and the conduct to be enjoined."). With regards to Plaintiffs' claim that Samsung's sublicense to Quallent constitutes a breach of the Settlement Agreement, the Court finds that there is a "significantly better than negligible" chance that Plaintiffs will succeed in showing that Samsung breached the Settlement Agreement. *See Touzot*, 2016 WL 1688089, at *7.

The chief object "of contract interpretation is to determine the intent of the parties." *Deluxe Bldg. Sys., Inc. v. Constructamax, Inc.*, Civ. No. 06-2996, 2016 WL 4150746, at *3 (D.N.J. Aug. 1, 2016) (quoting *Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 587 (3d Cir. 2009)). And "[t]he strongest objective manifestation of intent is the language of the contract." *Id.* (quoting *Baldwin v. Univ. of Pittsburgh Med. Ctr.*, 636 F.3d 69, 76 (3d Cir. 2011)).

The Settlement Agreement permits Samsung to enter into sublicenses, but in only three limited circumstances. Plaintiffs dispute that the Quallent sublicense is covered under any of these three exceptions. Samsung contends that Section 3.2(b) of the Settlement Agreement applies, which permits Samsung to grant sublicenses to "commercialization partners to import, sell and offer to sell SB17 Product on behalf of [Samsung]."[18] (ECF No. 8-3 at 6, § 3.2(c).) Samsung avers that Quallent will sell the product as a commercialization partner of Samsung and Sandoz. (ECF No. 19 at 37.) In support, Samsung cites language from the Quallent Sublicense Agreement, which provides in relevant part that "[Quallent] and/or its affiliates shall distribute the Products as

[18] In its opposition brief, Samsung appears to argue that Section 3.2(c) also applies, which allows Samsung to sublicense to "co-manufacture and commercialization partners to co-manufacture SB17 in coordination with Samsung and commercialize SB17 in the [United States] in the account of Samsung or the co-manufacture and commercialization party." (ECF No. 19 at 36-37.) However, at oral argument Samsung conceded that this exception does not apply. (*See* Tr. of Apr. 1, 2025 Hr'g at 61:14-21 ("[W]e're not relying on (c), but I think contextually it shows the breadth, and (b) is the critical provision here.").)

a *commercialization partner* of [Samsung] and Sandoz in the territory of the United States of America." (*Id.* at 36 (emphasis added).)

Plaintiffs argue that Quallent is not a commercialization partner acting *on behalf of* Samsung to fall within this exception. Plaintiffs assert that any other reading would render meaningless the term "on behalf of" in the Settlement Agreement. (*Id.*) The Court agrees. Giving the term "on behalf of" its plain and ordinary meaning, the Court finds that the Settlement Agreement does not contemplate that Samsung could authorize Quallent to sell ustekinumab under its own label. *See Kernahan v. Home Warranty Adm'r of Fla., Inc.*, 236 N.J. 301, 321 (2019) ("A basic tenet of contract interpretation is that contract terms should be given their plain and ordinary meaning."). Indeed, Black's Law Dictionary provides that "*on behalf of* means 'in the name of, on the part of, as the agent or representative of.'" Black's Law Dictionary (12th ed. 2024) (emphasis in original); *see also Sherwood Grp. Assocs. LLC v. Twp. of Union*, Civ. No. 14-3320, 2015 WL 1268189, at *5 (D.N.J. Mar. 17, 2015) ("[C]ourts generally rely on dictionaries to determine the plain meaning of contractual terms.").

Under the PLD, Quallent will be selling the product under its own label and under a different national drug code[19] than Samsung's Pyzchiva. (*See* ECF No. 19-5 § 1.6; *see also* ECF No. 43-1.) This leads the Court to conclude that Quallent will not be selling *on behalf of* Samsung as contemplated by the terms of the Settlement Agreement. The Court cannot excise "on behalf of" from this section of the Settlement Agreement, as Samsung's reading of the contract effectively does. *See A.D.L. v. Cinnaminson Twp. Bd. of Educ.*, 975 F. Supp. 2d 459, 466 (D.N.J. 2013)

[19] "Drugs are identified and reported using a unique, three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs." United States Food and Drug Administration, *National Drug Code Director* (last accessed Apr. 4, 2025), https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

("Under the basic precepts of contract construction, a document should not be interpreted to render one of its terms meaningless." (internal quotation marks omitted)).

The Court's narrow reading of "on behalf of" is consistent with its review of the contract as a whole. *Xiao-Wei Chou v. J.P. Morgan Chase*, Civ. No. 18-15407, 2020 WL 1272086, at *2 (D.N.J. Mar. 17, 2020) ("In New Jersey, contracts are interpreted by their 'plain language' and read 'as a whole in a fair and common sense manner.'" (quoting *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 255 (3d Cir. 2010))). The Court is not persuaded that, when viewed as a whole, the Settlement Agreement supports Samsung's position that its sublicense to Quallent is permissible. For one, pursuant to Section 3.1 of the Settlement Agreement, Plaintiffs granted Samsung a non-transferable license without the right to sublicense except as provided in Section 3.2. (ECF No. 8-3 at 5, § 3.1.) Section 3.2 clearly provides that Samsung's right to sublicence is "solely" limited to three exceptions, that any sublicense must be consistent with the terms and conditions of the Settlement Agreement, and it requires Samsung to disclose its sublicenses to Plaintiffs within 30 days. (*Id.* at 6, § 3.2.) And, Section 3.2 of the Settlement Agreement only applies to "Licensed Parties," which is defined solely as "Samsung and its Affiliates." (*Id.* at 3, § 1.1 and 6, § 3.2.) Moreover, the Settlement Agreement contains an anti-assignment clause which provides that "[n]o Party shall assign this Agreement or any part hereof or any interest herein . . . without the prior written consent of the other Party[.]" (ECF No. 8-3 at 14, § 10.12.) The anti-assignment clause includes exceptions only for: (1) "affiliates" of Samsung; and (2) Samsung's successor entities in the case of a merger or change in control. (*Id.*) Neither exception covers Samsung's PLD Agreement with Quallent, and there is nothing in the record to suggest otherwise. Taken as a whole, the Settlement Agreement does not contemplate such an expansive reading as argued by Samsung.

The Court also does not read the term "commercialization partner" as broadly as Samsung suggests. After entering into the Commercialization Agreement, Sandoz announced that it was granted "exclusive commercialization rights" to Samsung's biosimilar. (ECF No. 8-3 at 199.) That announcement is consistent with the terms of the Commercialization Agreement, which provides that Sandoz will be "solely responsible for performing and will use Commercially Reasonable Efforts to perform all activities relating to the Commercialization of [Pyzchiva] in the Territory at its own cost as set forth in the Commercialization Plan." (ECF No. 19-5 at 46, § 4.1.) The Commercialization Agreement requires Sandoz to provide Samsung its commercialization plans on an annual basis. (*Id.*) Further, the Commercialization Agreement includes a 9-page exhibit titled "Commercialization Activities," which other than the title was fully redacted by Samsung. (*See* ECF No. 19-5 at 99-107.)

In contrast, neither the PLD Agreement nor the Quallent Sublicense Agreement require Quallent to perform the type of commercialization activities as contemplated in the Commercialization Agreement, such as creating a commercialization plan. (*See generally* ECF No. 19-5 at 113-139; ECF No. 8-3 at 140-46.) Although these agreements refer to Quallent as a "commercialization partner," (*see, e.g.*, ECF No. 19-5 at 113), the substance of the agreements do not appear to support that notion. The Court does not give weight to Samsung's self-serving description of Quallent as a "commercialization partner." *See Van Horn v. Harmony Sand & Gravel, Inc.*, 122 A.3d 1021, 1027 (N.J. Super. Ct. App. Div. 2015) ("[The plaintiff] seeks to elevate form over substance, which violates the principle that we interpret agreements to determine the intent of the parties, rather than focus solely on the language used."); *Powerhouse First, LLC v. Waldo Jersey City, LLC*, 2016 WL 3503150, at *6 (N.J. Super. Ct. App. Div. June 28, 2016) (declining to rely on "self-serving statements" unsupported by the record).

For these reasons, the Court concludes that there is a "significantly better than negligible" chance that Plaintiffs succeed on their breach of contract claim.[20] *Tracey*, 451 F. Supp. at 342.

**2. *Breach of the Implied Covenant of Good Faith and Fair Dealing***

"In New Jersey, '[e]very contract contains an implied covenant of good faith and fair dealing.'" *Doe v. Princeton Univ.*, 30 F.4th 335, 348 (3d Cir. 2022) (quoting *Wade v. Kessler Inst.*, 172 N.J. 327, 340 (2002)). "The implied covenant prohibits either party from doing 'anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.'" *Id.* (quoting *Sons of Thunder, Inc. v. Borden, Inc.*, 690 A.2d 575, 587 (N.J. 1997)).

Plaintiffs argue that Samsung's conduct in allowing Quallent to sell a private label ustekinumab biosimilar "frustrates the purpose" of the Settlement Agreement, which prohibits the partial assignment of rights or interests. (ECF No. 8 at 32.) Thus, Plaintiffs assert that the Settlement Agreement "was not intended for Samsung to act as a clearing house to spin off additional [Stelara] biosimilars that will compete with both [Stelara] and other biosimilars." (*Id.* at 32-33.) Samsung does not directly attack Plaintiffs' implied covenant of good faith and fair dealing claim on the merits, instead arguing that Plaintiffs' breach of covenant claim is duplicative

[20] Plaintiffs spend considerable time arguing that Samsung, with the goal of bringing the Quallent sublicence within the scope of the Settlement Agreement, sought to impermissibly expand the Settlement Agreement after the fact by seeking an amendment that would redefine "product" (singular) to products (plural). (ECF No. 8 at 27.) Samsung counters that it sought the amendment to cover all three presentations of Pyzchiva. (ECF No. 19 at 34.) The Court does not find Plaintiffs' argument persuasive for purposes of interpreting the terms of the Settlement Agreement at this stage of the proceedings. Specifically, the Court is not convinced that it should consider the exchanges of counsel and proposed amendments that occurred following the execution of the Settlement Agreement, which includes a merger clause and expressly provides that amendments are only to be effective upon execution by both parties. (*See* ECF No. 8-3 at 13-14, §§ 10.5 and 10.8.) *See Swepco Tube LLC v. Loc. 427, IUE-CWA, AFL-CIO*, Civ. No. 07-767, 2008 WL 746670, at *4 (D.N.J. Mar. 18, 2008) ("[A] court is not authorized to construe a contract in such a way as to modify the plain meaning of its words, under the guise of interpretation.").

of their breach of contract claim. (*See* ECF No. 19 at 40-42.) The Court disagrees with Samsung's contention that the claims are necessarily duplicative.

Samsung is correct that in certain circumstances courts have dismissed breach of the implied covenant of good faith and fair dealing claims as duplicative. *See, e.g.*, *Grace's Dream, LLC v. PB Holdco, LLC*, Civ. No. 24-5651, 2025 WL 396756, at *6 (D.N.J. Feb. 5, 2025). The implied covenant of good faith and fair dealing cannot "override an express term in a contract" but "a party's performance under a contract may breach the implied covenant even though that performance does not violate a pertinent express term." *Wade v. Kessler Inst.*, 798 A.2d 1251, 1259-60 (N.J. 2002). In other words, "when a party breaches a duty set forth explicitly in a contract, the remedy exists pursuant to those express terms, and not pursuant to some implied obligation arising out of the contract." *TBI Unlimited, LLC v. Clear Cut Lawn Decisions, LLC*, Civ. No. 12-3355, 2013 WL 6048720, at *3 (D.N.J. Nov. 14, 2013); *see also Fields v. Thompson Printing Co.*, 363 F.3d 259, 271-72 (3d Cir. 2004) ("[W]here the terms of a contract are not specific, the implied covenant of good faith and fair dealing may fill in the gaps where necessary to give efficacy to the contract as written. But where the terms of the parties' contract are clear, the implied covenant of good faith and fair dealing will not override the contract's express language.").

A party may only pursue a breach of the implied covenant of good faith and fair dealing as "an independent cause of action" in three limited circumstances: (1) "to allow the inclusion of additional terms and conditions not expressly set forth in the contract, but consistent with the parties' contractual expectations"; (2) "to allow redress for a contracting party's bad-faith performance of an agreement, when it is a pretext for the exercise of a contractual right to terminate, even where the defendant has not breached any express term"; and (3) "to rectify a party's unfair exercise of discretion regarding its contract performance." *Hills v. Bank of Am.*, Civ.

No. 13-4960, 2015 WL 1205007, at *4 (D.N.J. Mar. 17, 2015) (internal quotation marks omitted) (quoting *Kumon N. Am., Inc. v. Timban*, Civ. No. 13-4809, 2014 WL 2812122, at *7-8 (D.N.J. June 23, 2014)).

Here, the Court finds that Plaintiffs' breach of the implied covenant of good faith and fair dealing claim is not duplicative of their breach of contract claim. And the Court finds that Plaintiffs are likely to succeed on that claim. Even if Samsung's sublicense to Quallent did not breach the literal terms of the Settlement Agreement, it was likely inequitable. *See Emerson Radio Corp. v. Orion Sales, Inc.*, 253 F.3d 159, 170 (3d Cir. 2001) ("New Jersey law also holds that a party to a contract can breach the implied duty of good faith even if that party abides by the express and unambiguous terms of that contract if that party 'acts in bad faith or engages in some other form of inequitable conduct.'").

Samsung's broad interpretation of the Settlement Agreement would effectively allow it to execute a virtually unlimited number of sublicenses so long as it describes them as "commercialization" agreements. (*See* Tr. of Apr. 1, 2025 Hr'g at 70:14-17.) Even if the plain language of the contract were to support that reading, the Court agrees that Samsung's actions likely violated the implied covenant of good faith and fair dealing. By Samsung entering into a private label agreement with Quallent, after Samsung separately contracted with Sandoz to commercialize its product, Samsung appears to have frustrated Plaintiffs' purpose for entering into the Settlement Agreement. As discussed above, the Settlement Agreement includes a broad anti-assignment clause and allows sublicenses in very limited circumstances, one of which permitted Samsung to execute an agreement with Sandoz to enable it to sell Pyzchiva in the United States, which all parties generally agree was proper. (*See* ECF No. 7; ECF No. 8 at 43 ("[T]he preliminary injunction would not restrain Samsung's lawful activity of selling its branded product, [Pyzchiva],

under BLA No. 761373[.]").) At the time of that agreement, Sandoz even announced that it had "exclusive commercialization rights" in Europe and North America. (ECF No. 8-3 at 31-32.) Samsung's agreement with Quallent radically expands the scope and plain language of the Settlement Agreement.

There is also evidence before the Court that private label biosimilars being offered directly by vertically integrated conglomerates, which "exercise vast control over huge swaths of the healthcare sector," including health care providers, pharmacies, pharmacy benefit managers, health insurers, and more, is a new phenomenon that may not have been anticipated at the time the Settlement Agreement was executed by the parties. (ECF No. 8-3 at 166.) The first private label biosimilar launched in August 2023, the month after the parties executed the Settlement Agreement. (ECF No. 8-1 ¶ 14.) As described by Plaintiffs' expert Dr. Popovian, "the Federal Trade Commission (FTC) has found that conglomerates favor coverage or formulary placement of their private-labeled biosimilar instead of another lower-priced biosimilar—hindering competition among manufacturers." (*Id.* ¶ 19.) According to Plaintiffs, the vertically integrated conglomerates benefit because their insurance companies can meet the Affordable Care Act's requirement that 80-85% of premium dollars be spent on medical care (also known as the medical loss ratio) without that money leaving their ecosystem. (ECF No. 8 at 39-40.) In light of this development, and Samsung's apparent attempt to capitalize on this new dynamic, the Court finds that Samsung's arrangement with Quallent likely frustrates Plaintiffs' right to receive the benefits of the Settlement Agreement as contemplated by the parties. *See Sons of Thunder, Inc.*, 690 A.2d 575, 587 (N.J. 1997); *Com. Ins. Servs., Inc. v. Szczurek*, Civ. No. 05-3536, 2006 WL 8457151, at *6 (D.N.J. Jan. 6, 2006) ("Although the implied covenant of good faith and fair dealing cannot override an express

term in a contract, a party's performance under a contract may breach that implied covenant even though that performance does not violate a pertinent express term.").

Plaintiffs also claim that there is evidence of bad faith, including the difference in Samsung's actions when it was negotiating with Sandoz versus Quallent. For example, Samsung notified Plaintiffs of its negotiations with Sandoz and entered into a confidentiality agreement so that it could provide Sandoz the Settlement Agreement. But when Samsung negotiated with Quallent, it did not seek Plaintiffs' approval to share the Settlement Agreement with Quallent. (ECF No. 8 at 15.) At this preliminary stage, the Court finds this evidence leans more towards a finding that Plaintiffs are likely to succeed on their breach of the implied covenant of good faith and fair dealing claim. *See Brunswick Hills Racquet Club, Inc. v. Route 18 Shopping Ctr. Assocs.*, 864 A.2d 387, 396 (N.J. 2005) ("As a general rule, subterfuges and evasions in the performance of a contract violate the covenant of good faith and fair dealing even though the actor believes his conduct to be justified.") (cleaned up).

**B. Irreparable Harm**

Although Plaintiffs have shown they are likely to succeed on the merits, Plaintiffs still "have the burden of demonstrating that they will be irreparably harmed if their motion for a preliminary injunction is not granted." *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp. 2d 666, 681 (D.N.J. 2007), *aff'd*, 566 F.3d 999 (Fed. Cir. 2009). This is "not an easy burden" to carry; it will be met only if Plaintiffs "demonstrate[] a significant risk that [they] will experience harm that cannot adequately be compensated after the fact by monetary damages. *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000) (citations omitted); *see also Reilly*, 858 F.3d at 179 n.4 ("[T]he availability of money damages for an injury typically will preclude a finding of irreparable harm."). Moreover "[t]he irreparable harm alleged must be actual and imminent, not merely speculative." *Moneyham v. Ebbert*, 723 F. App'x. 89, 92 (3d Cir. 2018).

The question before the Court is whether Plaintiffs' potential loss in market share from Samsung's breach of contract or breach of the implied covenant of good faith and fair dealing can be (1) calculated, and (2) compensated with money damages. *See Altana Pharma AG*, 532 F. Supp. 2d at 683 (noting there is no irreparable harm "where money damages are calculable and the defendants have the ability to pay any damages award" (citing *Eli Lilly and Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996))). As an initial matter, Plaintiffs do not appear to allege that Samsung would be unable to pay a judgment. *See Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991) (vacating preliminary injunction in part because the defendant was "acknowledged to be a large and financially responsible company which would be answerable in damages"). Thus, Plaintiffs' Motion turns on whether the damages stemming from Samsung's breach, specifically Plaintiffs' loss in market share,[21] are capable of being calculated. For the reasons set forth below, the Court finds that Plaintiffs have not shown that their damages would be incapable of calculation, and the Court will therefore deny Plaintiffs' Motion.

Plaintiffs argue that Samsung authorizing Quallent to sell a Stelara biosimilar presents the "classic irreparable injury" of an innovator suffering harm "due to unauthorized market entry of a generic or biosimilar." (ECF No. 8 at 34.) Plaintiffs maintain that beyond causing commercial harm, allowing Quallent into the market would result in Plaintiffs suffering harm that "is not quantifiable or redressable through monetary damages." (*Id.* at 37.) Plaintiffs also submit that the

[21] Plaintiffs do not appear to argue that Stelara will suffer from price erosion due to Samsung's breach. Nor do Plaintiffs argue that they will suffer other harms such as reputational damage or the inability to continue as a going concern, so the Court focuses on whether loss of market share constitutes irreparable harm here. Plaintiffs attempt to argue that they will suffer harm by way of a loss of negotiating power, but the Court finds that harm to be too speculative. *See Moneyham*, 723 F. App'x. at 92. Moreover, Plaintiffs have pointed the Court to no case in which a loss of negotiating power was sufficient to support preliminary injunctive relief.

potential harm here is "uniquely acute" because Quallent is a subsidiary of the vertically integrated Cigna Group.[22] (*Id.* at 34.)

To support their irreparable harm arguments, Plaintiffs rely on two declarations from health economist Dr. Robert Popovian. (ECF No. 8-1; ECF No. 23-2.) Plaintiffs argue that they will suffer irreparable harm if a Cigna subsidiary sells a Stelara biosimilar because Cigna controls 23% of prescriptions in the United States. (ECF No. 8 at 9.) According to Plaintiffs, "[i]nnovative pharmaceutical companies can struggle to compete with drugs controlled by conglomerates like the Cigna Group because their vertical integration enables and incentivizes them to steer patients towards their own drugs." (*Id.* at 37.) Plaintiffs argue that, due to the Cigna Group's market positioning, "Samsung's improper attempt to double the scope of its license by purporting to sublicense its rights to Quallent threatens significant diminution of [Stelara's] potential market share." (*Id.*) Plaintiffs and Dr. Popovian contend that Quallent's entrance into the market would affect Plaintiffs' market share "in ways that are entirely different from the ways that a biosimilar marketed at arms-length by Samsung and Sandoz will impact the market." (*Id.* at 38; ECF No. 8-1 ¶¶ 22-34.)

In terms of the Cigna Group's influence and control, Plaintiffs contend that "the Cigna Group can cause its captive health care provider Evernorth to craft particularized incentives for patients to seek out only the Quallent private label." (ECF No. 8 at 39.) From there, Cigna's subsidiaries, including its pharmacy benefit manager (PBM) Express Scripts, could "offer dramatically more favorable reimbursement rates to their specialty pharmacy (Accredo) if it fills prescriptions with the Quallent private label." (*Id.* at 39.) In turn, the Cigna Group could "offer

[22] The Cigna Group is a "global health company" which "owns a health care provider (Evernorth), an insurance company (Cigna Health Care), a PBM (Express Scripts), and a network of specialty pharmacies (Accredo)." (ECF No. 19-4 ¶ 10.)

dramatically less favorable reimbursement rates to third party pharmacies for" Stelara and other Stelara biosimilars. (*Id.*)

Samsung counters that the potential harms outlined by Plaintiffs are compensable by money damages.[23] Samsung relies on a declaration from economist Dr. DeForest McDuff.[24] (ECF No. 19-4.) Dr. McDuff states that any loss of market share suffered by Plaintiffs would be calculable, in part because "[t]he market for Stelara is . . . highly tracked by Johnson & Johnson and market observers, which makes the necessary data to quantify damages easier to obtain." (*Id.* ¶ 29.) Dr. McDuff opines that the biosimilar market has some similarities to the generic drug market, which would "facilitate the modeling of harm and thus make any damages more readily quantifiable." (*Id.* ¶ 27.) Moreover, Dr. McDuff contends that the Cigna Group's clearly defined market share would make calculating damages more straightforward. Specifically, Dr. McDuff notes that "the limitation of [Plaintiffs'] alleged harm to prescriptions controlled by Cigna makes damages more readily quantifiable, as any Cigna customers who are 'steered' toward the private label version of Samsung's biosimilar would be easily identifiable and attributable to Quallent." (*Id.* ¶ 28.) This is so, Dr. McDuff contends, because the "sales at issue [being] concentrated in a single customer group facilitate[s] the quantification of damages and do[es] not reflect likelihood of irreparable harm." (*Id.*) Finally, Dr. McDuff asserts that "[g]eneric entry in the pharmaceutical industry has been evaluated and modeled extensively in economic literature" and that the "effects

[23] Samsung also argues that Plaintiffs' damages are speculative and not imminent. For example, Samsung assert that Cigna's PBM typically updates its formularies on January 1st of each year, decreasing the likelihood that Stelara will be removed before January 1, 2026. As the Court finds that Plaintiffs are not entitled to a preliminary injunction on the grounds that any potential damages are redressable with money damages, the Court does not reach these arguments.

[24] Neither party challenges the qualifications of the other party's economic expert. The Court notes that Dr. Popovian's and Dr. McDuff's credentials are substantial.

of entry and competition for biologic drugs have been evaluated in published literature, where available evidence indicates that the effect is similar to generic entry." (*Id.* ¶ 27.)

Although, as Plaintiffs contend, a loss of market share can equate to irreparable harm in some cases, there is no such bright-line rule. *See CommScope, Inc.* 2021 WL 1560717, at *4 ("Loss of market share can establish irreparable harm in *some* circumstances." (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) (emphasis added))). Indeed, numerous courts have denied motions for preliminary injunctive relief where a party claimed they would suffer harms such as a loss in market share. *See, e.g.*, *Graceway Pharms., LLC v. Perrigo Co.*, 722 F. Supp. 2d 566, 579 (D.N.J. 2010) ("[The defendant] argues that the [p]laintiffs' structural claims, including lost jobs, price erosion, market share, and business reputation are compensable by money damages and readily calculable as Aldara is a mature product. . . . [T]his Court agrees."); *Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 500 (D.N.J. 2015) ("[The plaintiff] has not demonstrated that the loss of market share, sales, and/or price erosion, even if proven, constitute anything other than purely economic and reparable loss. . . ."); *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc.*, Civ. No. 05-1887, 2007 WL 2669338, at *14 (D.N.J. Sept. 6, 2007), *aff'd*, 280 F. App'x 996 (Fed. Cir. 2008) (holding that "[b]oth loss of market share and price erosion are economic harms and are compensable by money damages" and that courts "should not be swayed by the fact that money damages may be difficult to calculate"); *Sebela Int'l Ltd. v. Actavis Lab'ys FL, Inc.*, Civ. No. 17-4789, 2017 WL 4782807, at *7 (D.N.J. Oct. 20, 2017) ("[T]his Court has recognized that '[b]oth loss of market share and price erosion are economic harms and are compensable by money damages' even in the "context of generic competition in the pharmaceutical industry.") (citation omitted). *Cf. AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 610 (D.N.J.), *supplemented*,

623 F. Supp. 2d 615 (D.N.J. 2009), *and aff'd*, 633 F.3d 1042 (Fed. Cir. 2010) (granting preliminary injunctive relief based on the plaintiff's pre-existing contract which contemplated a market exclusivity period, but separately holding that "damages from loss of formulary positions are reasonably calculable" and that "[a]lthough significant, any damages [the plaintiff] might suffer as a result of loss of market share or profits are calculable and compensable").

Importantly, to obtain preliminary injunctive relief, Plaintiffs bear the burden of establishing that monetary relief would be unquantifiable or insufficient. *See Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239, 263 (D.N.J. 1997) ("To prove irreparable harm, [the plaintiff] must provide some 'reasoned analysis' for why monetary damages would be insignificant and it has not done so.") (quoting *Nutrition 21*, 930 F.2d at 869); *AstraZeneca LP*, 623 F. Supp. 2d at 608 (declining to find that loss of market share was irreparable, noting that "any damages [the plaintiff] might suffer as a result of loss of market share or profits are calculable and compensable"). At oral argument, Plaintiffs' counsel suggested that Samsung had not supported its assertion that Plaintiffs' damages would be calculable. (*See* Tr. of Apr. 1, 2025 Hr'g at 117:22-25("[Samsung] kind of hand wave[s] what the expert is saying, well, you know, you can see what their revenues are, you can see things like that. They never actually say that you could calculate the damages that way.").) But requiring Samsung to prove that damages are, in fact, quantifiable improperly shifts Plaintiffs' burden to Samsung. *See Everett Lab'ys, Inc. v. Acella Pharms., LLC*, Civ. No. 13-3470, 2013 WL 5179006, at *6 (D.N.J. Sept. 13, 2013) ("[T]he burden is on [the plaintiff] to show that any harm it will suffer cannot be remedied by damages at a later date.")

Plaintiffs' expert, Dr. Popovian, outlines in his initial declaration that Plaintiffs face the risk of losing significant market share if the Quallent private label product is allowed to enter the

market. Dr. Popovian writes that "Quallent's launch of a private label [Stelara] biosimilar can make a quarter of the entire patient population for [Stelara] inaccessible to [Plaintiffs] because Quallent is part of a vertically integrated healthcare conglomerate known as The Cigna Group that controls approximately 23% of the prescription market." (ECF No. 8-1 ¶ 10.) In opposition, Samsung correctly observes that Dr. Popovian "does not offer any reason such a loss would not be quantifiable or compensable by money damages." (ECF No. 19 at 24.)

Only in his reply declaration does Dr. Popovian attempt to address why Plaintiffs would be unable to calculate their damages if Samsung is found liable to Plaintiffs. Dr. Popovian asserts that "the long-term market harm of private label biosimilars controlled by the three companies that dominate the pharmaceutical prescription market is not quantifiable." (ECF No. 23-2 ¶ 7.) Under the heading "Private Label [Stelara] Biosimilars Are Not Pro-Consumer," Dr. Popovian states that vertically integrated conglomerates controlling the market "has the effect of reducing market share for the innovator (as well as other biosimilars)." (*Id.*) Dr. Popovian also contends that "it deters investment in biosimilars and will ultimately cause a contraction of competitive biosimilars, because biosimilar manufacturers cannot obtain fair access to the customers controlled by these vertically integrated companies that control the . . . market." (*Id.*) Next, Dr. Popovian asserts that "[Plainiffs] ha[ve] to negotiate with the Cigna Group with a sword over [their] head," noting that "[i]t is impossible to model what concessions [Plaintiffs] will make to continue to be within the ecosystem controlled by the Cigna Group that it would not have made if the Cigna Group did not have the right [to] sell a private label [Stelara]." (*Id.*) Finally, Dr. Popovian opines that "because the pricing market is so complex, it is impossible to model [how] the Cigna Group's behavior influences other actors." (*Id.*)

The Court does not find Dr. Popovian's opinion concerning the impossibility of calculating damages persuasive. Dr. Popovian primarily takes issue with vertically integrated conglomerates, like the Cigna Group, controlling a significant portion of the biologic sales industry; he does not, however, explain how that is relevant to *calculating* damages. Dr. Popovian's observation about the complexity of the pricing model for biologics is also insufficient to carry Plaintiffs' burden of showing that damages would not be quantifiable. *See Sebela Int'l Ltd. v. Actavis Lab'ys FL, Inc.*, Civ. No. 17-4789, 2017 WL 4782807, at *7 (D.N.J. Oct. 20, 2017) (denying request for preliminary injunction even though the plaintiff's damages were potentially "significant, and the complexities and uniqueness of the pharmaceutical industry might make such calculation an arduous task") (internal quotations and citation omitted). Indeed, granting preliminary injunctive relief because of the complexities of the pharmaceutical market would result in preliminary injunctions becoming the norm, rather than the exception. *See Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) ("Preliminary injunctive relief is an 'extraordinary remedy, which should be granted only in limited circumstances.'"). "[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21*, 930 F.2d at 871 ("[T]he district court's reliance on possible market share loss would apply in every patent case where the patentee practices the invention.").

The Court also notes a logical flaw in Dr. Popovian's position. Dr. Popovian uses the example of Humira, another branded biologic, to underscore the magnitude of harm faced by Plaintiffs. Dr. Popovian opines in his initial declaration that "[t]o examine the potential impact on market competition among biosimilars due to the introduction of PBM-owned private labels, we can examine the formulary placement of Humira (adalimumab) brand and biosimilar alternatives

regarding the formularies of the three primary PBMs." (ECF No. 8-1 ¶ 35.) Dr. Popovian goes on to explain that after CVS Caremark removed Humira from its formularies in favor of its own biosimilar from Cordavis, "new prescriptions of Humira dropped from 95% down to 64%, with 93% of the lost market share going to a biosimilar manufactured by Sandoz and sold under Cordavis's private label." (*Id.* ¶ 50.) Samsung argues that "[n]either [Plaintiffs] nor Dr. Popovian offer any reason the same analysis could not be performed to quantify any loss [Plaintiffs'] branded biologic Stelara may suffer due to a private label ustekinumab-ttwe." (ECF No. 19 at 25.) The Court agrees that Plaintiffs have offered no such explanation, and the Court finds that Plaintiffs have not provided a "reasoned analysis" to support their position that calculating damages would be impossible if Samsung is ultimately found to be in breach of the Settlement Agreement.

The cases cited by Plaintiffs for the proposition that their loss of market share in this case constitutes irreparable harm are also distinguishable. In *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, the United States Court of Appeals for the Third Circuit affirmed the district court's entry of a preliminary injunction enjoining the defendant from using certain marketing language to refer to its over-the-counter heartburn medication. 290 F.3d at 596. The district court concluded that the plaintiff was likely to succeed in proving that the defendant's labeling of its product as "Night Time Strength" would likely mislead consumers. *Id.* at 583, 590. In affirming the entry of a preliminary injunction, the Third Circuit was satisfied that the loss of market share allegedly caused by the plaintiff's false advertising constituted irreparable harm in that context. *Id.* at 595-96 ("We are satisfied that *this* loss of market share constitutes irreparable harm.") (emphasis added). However, the Court's ruling was limited to the facts in that case, which included claims of false advertising. Specifically, the Court reasoned that "[i]n a competitive industry where consumers are brand-loyal, we believe that loss of market share is a

potential harm which cannot be redressed by a legal or an equitable remedy following a trial." *Id.* at 596 (internal quotation marks omitted).

Here, Plaintiffs have not argued that Stelara users are brand loyal, or that Quallent's private label would cause any reputational harm to Plaintiffs. Samsung's expert, Dr. McDuff, states in his declaration that "any reputational harm to [Plaintiffs'] goodwill or reputation with customers is unlikely [because] the entry of lower cost alternatives is typical for biologics and biosimilars and would be expected to occur eventually." (ECF No. 19-4 ¶ 59.) Plaintiffs do not argue otherwise or attempt to rebut Dr. McDuff's assertion. To the contrary, public statements by Plaintiffs' senior leaders show that they fully expected increases in biosimilar competition. (See ECF No. 19-4 ¶ 42 (statement from Johnson & Johnson's Chief Financial Officer that "we knew for a few years now that Stelara would face biosimilar competition, and so we had to be prepared" and that "the strength of our portfolio enables innovative medicine to grow despite expanded biosimilar competition.").) For these reasons, the Court finds *Novartis* distinguishable from this case.

Plaintiffs also rely on *Abbott Laboratories v. Sandoz, Inc.*, a case in which the Federal Circuit affirmed the district court's grant of a preliminary injunction in a patent infringement suit related to generic pharmaceuticals. 544 F.3d 1341, 1343 (Fed. Cir. 2008). Before the district court, the plaintiff argued that it would "suffer loss of market share, goodwill, and profits; w[ould] be constrained to terminate 190 sales representatives; and w[ould] face losses that w[ould] never be fully compensable in money damages." *Abbott Lab'ys v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 843 (N.D. Ill. 2007). Further, the plaintiff argued that it would "face a 90% decline in market share" along with losing its "preferred position on pharmacy and insurance formularies." *Id.* at 843. The district court concluded that the defendant's sale of its generic drug would "crush the market." *Id.*

at 843. The Federal Circuit held that the district court had not abused its discretion in granting a preliminary injunction. *Abbott*, 544 F.3d at 1343.

Samsung asserts that *Abbott* is inapposite because the district court applied a presumption of irreparable harm, which used to apply in patent suits when a party "made a clear showing of both infringement and validity."[25] (ECF No. 19 at 21.) Plaintiffs, however, dispute that *Abbott* involved such a presumption. (ECF No. 23 at 8.) Plaintiffs find support in that argument from the Federal Circuit's opinion affirming the district court's ruling, which concluded that "[t]he district court did not apply [a presumption of entitlement to an injunction upon a finding of likelihood that a patent will be sustained and found infringed], but fully considered all of the legal and equitable factors." *Abbott*, 544 F.3d at 1363.

Regardless of whether the district court applied a presumption of irreparable harm, *Abbott* is not binding precedent in this breach of contract case. And even if the Court were to find the reasoning in *Abbott* persuasive, that case is factually distinguishable. Importantly, the potential for a 90% loss of market share that existed in that case does not exist here. Plaintiffs argue that the Cigna Group will exert its control over 23% of prescriptions in the United States to Plaintiffs' detriment. (ECF No. 8 at 24; ECF No. 8-1 ¶ 11.) Moreover, considering that there are at least four biosimilars of Stelara currently on the market, with more to enter the market in 2025, the Court is not persuaded that Quallent's introduction of its private label biosimilar will "crush the market" for Stelara.

[25] Following the United States Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), the Federal Circuit "jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

Plaintiffs also rely on *King Pharms., Inc. v. Corepharma, LLC*, Civ. No. 10-1878, 2010 WL 1850200 (D.N.J. May 7, 2010). There, the court found that a pharmaceutical company would suffer irreparable harm upon the entry of a potentially unauthorized generic into the market. The court concluded that "the presence of two generics in the marketplace will extremely erode [the plaintiff's] market share and also make the drug subject to [Maximum Allowable Cost (MAC)] pricing."[26] *Id.* at *4. Samsung argues that *King Pharms., Inc. v. Corepharma* is inapposite because the court there found that the plaintiff would be harmed only during the two and a half years that the defendant was not permitted to enter the market. (ECF No. 19 at 21-22.) Because Samsung is already permitted to sell ustekinumab-ttwe in the United States, Samsung contends that "the only period of time during which [Plaintiffs] would suffer harm under the logic of *King Pharmaceuticals* has already passed." (*Id.* at 22.) The Court agrees, as there are already other biosimilars on the market. (ECF No. 19-4 ¶ 45.) The Court further notes that the theory of irreparable harm in *King Pharmaceuticals* rested in part on price erosion, which Plaintiffs have not raised here.[27]

Finally, in *Everett Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, the court found that the loss of market share caused by the defendant's entry into the market with a generic version of the plaintiff's nutritional supplement would cause harm that could not be "quantified for the

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[26] The court noted that MAC pricing "is a formula used to calculate the maximum amount that third party payors will pay for a drug, and is only used when there are three drugs on the market." *King Pharms., Inc. v. Corepharma*, 2010 WL 1850200, at *4 n.2. Neither party has raised this as an issue in this case.

[27] Just ten days after the court's grant of a preliminary injunction in *King Pharms., Inc. v. Corepharma*, the court in the related case of *King Pharms., Inc. v. Sandoz, Inc.*, held that the same plaintiffs failed to show they would be irreparably harmed by a generic's entry into the market, observing that "in cases where the presumption [of] irreparable harm is not available . . . courts have routinely decided that market share and price erosion do not amount to irreparable harm. Civ. No. 08-5974, 2010 WL 1957640 (D.N.J. May 17, 2010) (internal citation omitted).

purposes of awarding money damages." 573 F. Supp. 2d 855, 867-68 (D.N.J. 2008). The court held that "in the context of this product and the marketing strategies involved it will be impossible to measure the amount of lost market share due to the presence of other competitive products on the market." *Id*. at 868. In particular, the court agreed that the plaintiff faced a "Hobson's choice" under which the plaintiff's promotion of its product would end up indirectly steering more customers to the defendant's product as "third-party payor computer program[s] pick[] the less expensive 'generic.'" *Id.* at 868. However, the court cabined its holding on loss of market share constituting irreparable harm to the specific facts of the case and its inability to quantify the defendant's loss of market share. *See id.* at 868 ("The Court agrees that loss of market share is difficult to quantify *in this context* and thus, constitutes irreparable harm.") (emphasis in original).

The court in *Everett* acknowledged that its finding of irreparable harm was "inapposite to its recent decision in *Altana* [*Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007)], where it found that loss of market share did not constitute irreparable harm for purposes of a preliminary injunction." *Id.* at 868 n.9. The Court explained that *Altana* was distinguishable because the drug there was FDA-approved and subject to the protections of the Hatch-Waxman Act. *Id.* The court reasoned that "[u]nder Hatch-Waxman, a drug has a period of exclusivity such that loss of market share is easy to quantify upon entry of one other generic drug into the market whereas in this instance, there is no exclusivity period and the market is already divided between the patented product and its competitors." *Id.*

Even if calculating the market share potentially lost by Plaintiffs here may not be as "easy" as in *Altana* because of the presence of other biosimilar competitors, that factor alone is not sufficient to establish irreparable harm. Indeed, courts have found a lack of irreparable harm even where a damages calculation would be difficult, so long as calculating damages is feasible. *See*

*Otsuka Pharm. Co.*, 99 F. Supp. 3d at 500 ("Nor has [the plaintiff] demonstrated that these losses are incapable of calculation. Rather, [the plaintiff] demonstrated, at most, that the exact calculation of the damages may prove a difficult endeavor, but that too fails to make a sufficient case for irreparable harm."); *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, Civ. No. 15-819, 2016 WL 4770244, at *19-20 (D. Del. Aug. 12, 2016) *report and recommendation adopted*, Civ. No. 15-819 at ECF No. 185 ("Estimating future damages with less than perfect information is never easy. . . . But there are plenty of data points for [the p]laintiffs' expert to work with in that effort. In light of that, and [the p]laintiffs' insufficient showing regarding imminent and substantial harm, [the p]laintiffs have not met their burden to demonstrate that monetary damages would inadequately compensate any such harm."). As noted by Samsung's expert Dr. McDuff, the extensive data on Stelara's sales and the biosimilar and generic drug markets will assist with calculating potential damages here. (*See* ECF No. 19-4 ¶ 29.)

Accordingly, the Court finds that Plaintiffs have not established that they will suffer irreparable harm in the absence of a preliminary injunction. Plaintiffs' Motion for a Preliminary Injunction is denied. *See Ace Am. Ins. Co. v. Wachovia Ins. Agency Inc.*, 306 F. App'x 727, 732 (3d Cir. 2009) ("A failure to demonstrate irreparable injury must necessarily result in the denial of a preliminary injunction.").[28]

**C. Remaining Factors**

Since Plaintiffs have not established that they are likely to suffer irreparable harm in the absence of a preliminary injunction, the Court will not consider the last two factors of the

[28] In addition to asking the Court to enjoin Samsung from launching the Quallent private label biosimilar product, Plaintiffs also seek an order requiring Samsung to comply with the disclosure obligations in the parties' Settlement Agreement. (ECF No. 7.) Plaintiffs provide no basis to support that they would suffer irreparable harm absent immediate disclosure of the requested documents. Plaintiffs may seek these documents in the normal course of discovery.

preliminary injunction analysis. *See Spring Creek Rehab. & Nursing Ctr. LLC v. Nat'l Lab. Rels. Bd.*, Civ. No. 24-09016, 2024 WL 4563789, at *2 (D.N.J. Oct. 24, 2024) ("Only when a plaintiff has sufficiently met the first two prongs, does the Court consider the third prong relating to the possibility of harm to other parties and finally, evaluate whether public interest is served by granting injunctive relief.") (citation omitted); *see also Reilly*, 858 F.3d at 179 ("[T]he first two factors of the [preliminary injunction] standard are the most critical.") (citation omitted).

## IV. CONCLUSION

For the foregoing reasons, and other good cause shown, Plaintiffs' Motion for a Preliminary Injunction (ECF No. 7) is **DENIED**. An appropriate Order follows.

Dated: April 28, 2025

GEORGETTE CASTNER
UNITED STATES DISTRICT JUDGE